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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,888	07/19/2001	David Lewis	206451US6PCT	8005
22850	7590	02/13/2007	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			MITCHELL, TEENA KAY	
		ART UNIT	PAPER NUMBER	
		3771		
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	02/13/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/831,888	LEWIS ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Teena Mitchell	3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 31 March 2003.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 11-44 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 11-44 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date 12/18/03; 4/30/04; 11/22/04; 11/06/05;
- 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 27, 31, 35-37, 41, and 42 respectively of U.S. Patent No. 7,018,618. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application can be found in claims 22, 35, 36, 41 and 42 of the patent '618 it would have been obvious to combine the limitations into an independent claim as claim 22 of the instant application as all the elements of the claim are in claims 22, 35, 36, 41, and 42 of the patent. Claim 12 of the instant application limitations can be found in claim 22 of patent '618. Claim 14 of the instant application can be found in claim 26 of

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patent '618. Claim 15 of the instant application can be found in claim 26, 27 and 31 of patent '618. Claim 16 of the instant application can be found in claim 37 of patent '618. Claim 17 of the instant application can be found in claim 35 of patent '618. Claim 18 of the instant application can be found in claim 41 of patent '618. Claim 19 of the instant application can be found in claim 41 of patent '618.

**Claims 20-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22, 27, 31, 35-37, 41, and 42 respectively of U.S. Patent No. 7,018,618 in view of Jager et.al. (6,143,277) (6,143,277).** The difference between patent '618 and claims 20-44 is the specific active ingredients. Jager in a MDI teaches the claimed active ingredients (Col. 2, lines 52-67; Col. 4, lines 1-67; Col. 5, lines 1-10), it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed active ingredients as such active ingredients are well known in the art as taught by Jager.

**Claims 11-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 7, 10, 14, 15, 19, 22-29 respectively of U.S. Patent No. 6,713,047.** Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 11 of the instant application limitations can be found in claims 1, 10, 14, and 15 of patent '047 the combining of the claims would have been obvious to one of ordinary skill in the art as the limitations can be found in claims 1, 10, 14, 15, 19 of patent '047. Claim 12 of the instant application can be found in claims 1 and 10 of patent '047. Claim 13 of the instant application limitations can be found in claim 7 of patent '047. Claim 14 of the

instant application can be found in claims 14 and 21 of patent '047. Claim 15 of the instant application can be found in claims 22-29 of patent '047. Claim 16 of the instant application can be found in claims 6 and 10 of patent '047. Claim 17 of the instant application can be found in claims 1 and 15 of patent '047. Claim 18 of the instant application can be found in claim 14 of patent '047. Claim 19 of the instant application can be found in claim 14 of patent '047. Claim 20 of the instant application can be found in claims 1, 7, 14, 15, and 22-23 of patent '047.

**Claims 21-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 7, 10, 14, 15, 19, 22-29 respectively of U.S. Patent No. 6,713,047 in view of Jager.** The difference between patent '618 and claims 20-44 is the specific active ingredients. Jager in a MDI teaches the claimed active ingredients (Col. 2, lines 52-67; Col. 4, lines 1-67; Col. 5, lines 1-10), it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the claimed active ingredients as such active ingredients are well known in the art as taught by Jager.

**Claims 11-23,26,28, 31-34, 37, 39, 42, 43, and 44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6, 8, 10, and 11 respectively of copending Application No. 11/289,479.** Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 11 of the instant application limitations can be found in claims 1 and 3 of application '479. Claim 12 of the instant application limitations can be found in claim 6 of application '479. Claim 13 of the

instant application limitations can be found in claim 8 of application '479. Claims 14, 15, 21-23, 26, 28, 32-34, 37, 39, 42, 43, and 44 of the instant application limitations can be found in claim 2 of application '479. Claim 16 of the instant application can be found in claim 11 of application '479. claim 17 of the instant application can be found in claim 10 of application '479. Claims 18 and 19 of the instant application limitations can be found in claim 3 of application '479. Claim 20 of the instant application can be found in claims 1-3 of application '479, it would have been obvious to one of ordinary skill in the art to combine the limitations of claims 1-3 of application '479 into one dependent claim as the '479 application claims have the same limitations. Claim 31 of the instant application limitations can be found in claims 2, 8, 10, and 11 of application '479.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11, 15, 16, and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 12, 14, 17, 18, and 20 respectively of copending Application No. 10/505,861. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the instant application limitations can be found in claims 1, 12, 17, 18, and 20 of application '861, the combination of the limitations of the claims of application '861 would have been obvious to one of ordinary skill in the art as the limitations of claim 11 of the instant application are in the claims of application '861 and combining claims 1, 12, 17, 18, and 20 into one claim would be an obvious combination. Claim 15 of the instant application can be found in claim 20 of application '861. Claim

16 of the instant application limitations can be found in claim 14 of application '861.

Claim 17 of the instant application limitations can be found in claim 12 of application '861.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

**and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).**

**Claims 11-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jager et.al. (5,676,930) in view of Britto (6,253,762).**

Jager in a pressurized metered dose inhaler discloses a solution comprising an active ingredient, a hydrofluorocarbon propellant, and a cosolvent (Abstract, col. 2, lines 20-67).

The difference between Jager and claim 11 is the inhaler having an internal surface material selected from the group consisting of stainless steel and anodized aluminum.

Britto in an MDI teaches an inhaler internal surface material selected from the group consisting of stainless steel and anodized aluminum coated with fluorocarbon polymer providing a means to reduce or essentially eliminates the problem of adhesion or deposition of fluticasone propione on the can walls and thus ensuring consistent delivery of medication in aerosol from the MDI (Col. 1, lines 55-67 and Col. 4, lines 33-67-Col. 7, lines 1-39).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any well-known material for the internal surface of the inhaler of Jager because doing so would have provided a means to reduce or essentially eliminates the problem of adhesion or deposition of fluticasone propione on

the can walls and thus ensuring consistent delivery of medication in aerosol from the MDI as taught by Britto.

With respect to claim 12, Jager discloses wherein said solution further comprises a low-volatility component (Col. 4, lines 56-67 and Col. 5, lines 1-10).

With respect to claim 13, Jager discloses wherein said low-volatility component is selected from the group consisting of propylene glycol, glycerol, polyethylene glycol, and isopropyl myristate (Col. 4, lines 56-67 and Col. 5, lines 1-10).

With respect to claim 14, Jager discloses wherein said active ingredient is selected from the group consisting of B2 agonists, steroids, anticholinergic agents, and mixtures thereof (col. 3, lines 36-67 and Col. 4, lines 1-28).

With respect to claim 15, Jager discloses wherein said active ingredient is ipratropium bromide, oxitropium bromide, and tiotropium bromide (Col. 4, lines 1-29).

With respect to claim 16, Jager discloses wherein said co-solvent is ethanol (Col. 5, lines 1-10).

With respect to claim 17, Jager discloses wherein said propellant is HFA 227, HFA 134a and mixtures thereof (Col. 2, lines 52-67).

With respect to claim 18, Britto teaches wherein part or all of said internal surface is stainless steel (Col. 1, lines 55-67 and Col. 4, lines 33-67-Col. 7, lines 1-39).

With respect to claim 19, Britto teaches wherein part or all of said internal surface is anodized aluminum (Col. 1, lines 55-67 and Col. 4, lines 33-67-Col. 7, lines 1-39).

With respect to claim 20, Jager discloses wherein said solution comprises a low-volatility component selected from the group consisting of propylene glycol, glycerol,

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polyethylene glycol, and isopropyl myristate (Col. 4, lines 64-67 and Col. 5, lines 1-10); said active ingredient is selected from the group consisting of B-adrenergic agonists, ipratropium, oxitropium bromide, tiotropium bromide (Col. 4, lines 1-29), said co-solvent is ethanol (Col. 5, lines 5-10); said propellant is selected from the group consisting of HFA 227, HFA 134a, and mixtures thereof (Col. 2, lines 52-67); and Britto teaches part or all of said internal surface is stainless steel (Col. 1, lines 55-67 and Col. 4, lines 33-67-Col. 7, lines 1-39).

With respect to claim 21, Jager discloses wherein said active ingredient is ipratropium bromide (Col. 4, lines 1-29).

With respect to claim 22, Jager discloses wherein said active ingredient is oxitropium bromide (Col. 4, lines 1-29).

With respect to claim 23, Jager discloses wherein said active ingredient is tiotropium bromide (Col. 4, lines 1-29).

With respect to claim 31 see rejection of claim 20 above.

With respect to claim 32, Jager discloses wherein said active ingredient is ipratropium bromide (Col. 4, lines 1-29).

With respect to claim 33, Jager discloses wherein said active ingredient is oxitropium bromide (Col. 4, lines 1-29).

With respect to claim 34, Jager discloses wherein said active ingredient is tiotropium bromide (Col. 4, lines 1-29).

With respect to claim 42, Jager discloses wherein said active B-adrenergic agonist is formoterol (Col. 4, lines 23-28).

With respect to claim 43, Jager discloses wherein said active B-adrenergic agonist is formoterol (Col. 4, lines 23-28).

With respect to claim 44, Jager discloses wherein said active B-adrenergic agonist is formoterol (Col. 4, lines 23-28).

With respect to claim 24, while Jager does not disclose the specific ingredient flunisolide. He does disclose that anti-inflammatories can be used. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the active ingredient to be flunisolide as such is a well-known anti-inflammatory drug (Col. 4, lines 1-32).

With respect to claims 25, 26, 28-30, 35-37, 39-41 note rejection of claim 24 above.

With respect to claims, 27 and 38, while Jager does not disclose the specific ingredient mometasone furoate. He does disclose that steroids can be used. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the active ingredient be mometasone furoate as such is a well-known corticosteroid (Col. 4, lines 1-32).

#### ***Response to Arguments***

Applicant's arguments with respect to claims 11-44 have been considered but are moot in view of the new ground(s) of rejection.

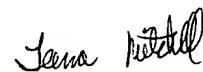
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-

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4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Teena Mitchell  
Primary Examiner  
Art Unit 3771  
February 6, 2007

TKM  
TKM